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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,211	10/23/2001	Arnold W. Fogel	B30-050	2238
7590	09/21/2004		EXAMINER	
Henry D. Coleman Coleman Sudol Sapone, P.C. 714 Colorado Avenue Bridgeport, CT 06605-1601			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,211	FOGEL, ARNOLD W.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 June 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3-8,10-25 and 27-36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3-8,10-25 and 27-36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/7/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Applicant's amendments filed June 18, 2004 have been entered.

The cancellation of claims 2, 9, and 26 in amendments filed June 18, 2004 is acknowledged.

Claims 1, 3-8, 10-25, and 27-36 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high water content" in claim 1 is a relative term which renders the claim indefinite. The term "high water content" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to how much water in the instant composition would be considered as "high content". Is 40% considered as high? Or 49% is considered high?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-8, 10-25, and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogel (US Patent 6,126,949 from the IDS received June 11, 2002), Herstein (US Patent 5,902,591), and McCutcheon (McCutcheon's Emulsifiers & Detergents North American Edition, 2000, 2000, page 18), references of record.

Fogel teaches the instant component A, a dialkyl fumarate, especially dibehenyl fumarate, is useful in harden or stiffen any cosmetically acceptable oil or water-in-oil emulsions and to enhance the stability of water-in-oil emulsion (See particularly the abstract). Fogel also teaches the emollients may be used with dibehenyl fumarate as petrolatum, mineral oil, various vegetable oils such as sunflower oil and safflower oil, and neopentanoates such as octyl dodecyl neopentanoate (See col. 3, line 65 - col. 4, line 59; also col. 10, line 64 in example 5). Fogel also teaches that the water-in-oil emulsion may contain 20-25% to 55-60% of water and 40-45% to 75-80% of emollient oil (See col. 5, line 31-33). Fogel also teaches that nonionic emulsifiers may be used in the water-in-oil emulsion (See col. 6, line 25).

Herstein teaches that a 5-10% of vitamin C containing topical cosmetic composition employing several preferred emulsifiers: one of which is stearic monoethanolamide (the instant preferred component C) (See the abstract and also col. 5, line 23).

McCutcheon teaches the Arlacel P135, the instant preferred component B, is useful as an emulsifier for cosmetic use (See page 18, col. 2).

The references do not expressly teach the three components can be incorporated into a single composition. The references do not expressly teach the specific weight ratio of the three components as 1-15% of component A, 1-15% of component B; and the ratio among components A, B, and C as 1:1:1: or 3:2:3. the references do not expressly teach te water content as 60%.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the three components herein into a single composition in the weight ratio herein and adjust the water content herein.

One of ordinary skill in the art would have been motivated to incorporate the three components herein into a single composition in the weight ratio herein and adjust the water content herein because component B and C are known, based on the cited prior art, to be useful as emulsifiers in water-in-oil emulsion. Combining two agents, which are known to be useful as emulsifiers individually into a single composition useful for formulating an emulsion composition, is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069). Moreover, dibehenyl fumarate, component A, is known to be useful to enhance the stability of water-in-oil emulsion. Therefore, further incorporating

component A into the emulsion composition containing component B and C would have been reasonably expected to be useful in stabilizing the resulting emulsion composition. In addition, the optimization of result effect parameters (e.g., weight ratio or amount of the components including water) is obvious as being within the skill of the artisan, absent evidence to the contrary. No such evidence is seen herein.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, no data was set forth in the specification for demonstrating the unexpected result. Therefore, no unexpected results are seen herein.

Response to Arguments

Applicant's arguments filed June 18, 2004 averring the cited prior art's failure to teach the unexpected benefits of the herein claimed combination of specific three agents in the herein claimed weight ratio have been considered, but are not found persuasive. Examiner notes that applicant has the burden to demonstrate unexpected

benefits. In the instant case, no unexpected results are seen herein. Therefore, the claims are still considered properly rejected under 35 USC 103(a).

Applicant's arguments filed June 18, 2004 averring an emulsion will readily separated into more than one phase when substantial amounts of water is present have been considered, but are not found persuasive. It is not clear why emulsion will be destabilized when substantial amount of water is present. It is not clear what "substantial" is referring to. Is 60% of water or 50% of water substantial amount of water? It is often to see water content in emulsion as more than 50%. Applicant has not provided any evidence in supporting such phenomenon.

Applicant's arguments filed June 18, 2004 averring Fogel's failure to teach the herein claimed ratio of the components have been considered, but are not found persuasive. Examiner notes that applicant has failed to demonstrate the criticality of the specific herein claimed weight ratio of the herein claimed components. Absent evidence to the contrary, optimization of the herein claimed amount would be seen as within the purview of skilled artisan.

Applicant's arguments filed June 18, 2004 averring Herstein's failure to teach a stabilized emulsion without the organoclay or hydrophilic gelling agent in the emulsion composition have been considered, but are not found persuasive. Examiner notes that the instant claims recite the ransitional phrase "consisting essentially of". The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic of the claimed invention. For the purpose of searching for and applying

prior art under 35 USC 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)(“Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant’s burden to establish that a step practiced in a prior art method is excluded from his claims by ‘consisting essentially of’ language.”) (See MPEP 2111.03). IN the instant case, applicant has the burden to demonstrate the addition of organoclay or hydrophilic gelling agents affect the basic and novel characteristic of the claimed composition. Absent evidence of showing the effect, the claims are seen to be properly rejected under 35 USC 103(a).

Applicant's arguments filed June 18, 2004 averring the "cherry-picking" of McCutcheon's teachings have been considered, but are not found persuasive. To show that the herein claimed components as commonly used in the art, McCutcheon was cited. The herein claimed components are well-known to be useful as emulsifying agents. Combining two agents (i.e., components B and C), which are old and well-known to be useful as emulsifiers individually into a single composition useful for formulating an emulsion composition, is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069). Absent evidence to the contrary, possessing the teachings of the cited prior art, one of ordinary skill in the art would have been motivated to combine any known emulsifiers taught in McCutcheon with the herein claimed components to form emulsions. Moreover, dibehenyl fumarate, component A, is known to be useful to enhance the stability of water-in-oil emulsion. Therefore, further incorporating component A into the emulsion composition containing component B and C would have been reasonably expected to be useful in stabilizing the resulting emulsion composition.

Applicant's arguments filed June 18, 2004 averring hindsight reconstruction by the examiner have been considered, but are not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*,

443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, as discussed above, the cited prior arts render the instant claims obvious. The motivation to combine the teachings of the cited prior arts is provided in the art. Component B and C are known, based on the cited prior art, to be useful as emulsifiers in water-in-oil emulsion. Combining two agents, which are known to be useful as emulsifiers individually into a single composition useful for formulating an emulsion composition, is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069). Moreover, dibehenyl fumarate, component A, is known to be useful to enhance the stability of water-in-oil emulsion. Therefore, further incorporating component A into the emulsion composition containing component B and C would have been reasonably expected to be useful in stabilizing the resulting emulsion composition. In addition, the optimization of result effect parameters (e.g., weight ratio or amount of the components) is obvious as being within the skill of the artisan, absent evidence to the contrary. No such evidence is seen herein.

Applicant's arguments filed June 18, 2004 with regard to *In re Dembiczkak [et al.]* ((175 f.3d 994), 50 USPQ2d 1614 (CAFC 1999) have been considered, but are not found persuasive. *Dembiczkak* deals with an orange plastic trash bag improved to resemble a jack-o'-lantern. The court found no motivation, save hindsight, linking the examiner cited prior art. To obviate, the examiner must provide "evidence of a suggestion, teaching or motivation to combine" flowing from "the prior art teaches themselves, the knowledge of one of ordinary skill in the art, or, in some cases from the nature of the problem to be solved." (See *In re Dembiczkak, supra* 1617). In the instant

case Examiner employs all three above suggestions to combine motivating the proffered obvious rejections. Each element employed in the instant claimed component is old and well known for emulsifying properties. Thus, those compounds herein employed would have been seen as a homogenous group of compounds linked by a common properties and use. Possessing a use for a common properties and use, these compounds would have been seen as logical alternatives to be employed for formulating emulsion.

Applicant's arguments filed June 18, 2004 averring the cited prior art's failure to suggest optimization have been considered, but are not found persuasive. As discussed above, the criticality of the specific herein claimed weight ratio has not been demonstrated. Absent such evidence, the weight ratio, which is considered as various range of amounts of the active ingredients, would be reasonably expected to be optimized as within the purview of one of ordinary skill in the art.

Applicant's arguments filed June 18, 2004 have been fully considered but they are not persuasive. Applicant argues that contrary to Examiner's citation of *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), it is not necessarily *prima facie* obvious to combine two or more components, each of which is taught by the prior art to be useful for the same purpose. In support of his assertion applicant cites to *In re Geiger*, 2 USPQ2d 1276 (Fed. Cir. 1987). Note that the court's analysis in *Geiger* was based on the notion of "non-analogous" art and the combining of elements from different (i.e., non-analogous) arts. The case at bar is therefore distinguishable from *Geiger*. Here, components B and C are known to be useful as emulsifiers in the cosmetics. The idea

of combining them flows logically from their having been individually taught in the prior art, *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Combining these various components into a single composition would have therefore been obvious, absent evidence to the contrary. No such evidence is seen.

Applicant's arguments filed June 18, 2004 averring the superior storage stability of the herein claimed composition have been considered, but are not found persuasive. There is no data as to the stability of the herein claimed composition shown in the instant specification. It is applicant's burden to demonstrate unexpected superior results (in this case, superior stability) in order to obviate the rejection under 35 USC 103(a). No such evidence is seen herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui
Patent Examiner
Art Unit 1617